

REMARKS

This amendment is provided in response to the Office Action mailed October 22, 2002. Favorable reconsideration of the subject matter is respectfully requested in view of the above amendments and following remarks. With this amendment, claims 1, 2, 9-11, 12, 14, 16, 17, 18, 19-34, and 36 are pending in the application. Claims 1, 9-11, 17, 19-34 have been withdrawn from consideration as being drawn to the non-elected groups. Claims 2-8, 12-16, 18, and 35-36 are currently under examination. Claims 3-8, 13, 15, and 35 have been cancelled. Claims 2, 12, 14, 16, 18, and 36 have been amended for clarity. It is urged that support for all these amendments may be found throughout the specification as originally filed and that no new matter is added to the application. The amendments are not to be construed as acquiescence to any rejection and are made without prejudice to prosecution of any subject matter cancelled or modified by the amendment in a related divisional, continuation, or continuation-in-part application.

Priority

Applicants note that claims 2, 12, and 18 get priority as of 02/26/2001

Specification – Informalities

The specification has been amended to update the status of parent U.S. applications in the first page of the Specification.

The specification has been amended to add the phrase “We claim” at the beginning of the claims.

Claim rejections under 35 U.S.C. 112 first paragraph

Claims 2, 12, 16, 18, and 36 stand rejected under 35 U.S.C. 112, first paragraph, on the alleged grounds that the specification, while being enabling for a isolated polypeptide comprising SEQ ID NO: 195, a fusion protein comprising SEQ ID NO: 195, and a composition comprising SEQ ID NO: 195, does not reasonably provide enablement for an isolated polypeptide comprising at least 70% and 90% sequence identity with SEQ ID NO: 195, a fusion protein and a composition comprising said polypeptide. More specifically, the Action alleges

that one skilled in the art would not be able to make and use polypeptides with at least 70% and 90% sequence identity with SEQ ID NO: 195 without undue experimentation.

Applicants respectfully traverse these grounds of rejection and submit that claims 2, 12, 16, 18, and 36 are supported by a specification, which enables one of ordinary skill in the art to make and use the invention as claimed without undue experimentation. Nonetheless, solely in order to expedite prosecution of the instant application, claim 2 has been amended to remove the subject matter of polypeptides having at least 70% or 90% sequence identity to SEQ ID NO: 195. Claims 12, 16, 18, and 36 have been amended to depend solely from newly amended claim 2 and therefore are directed towards the subject matter of isolated polypeptides comprising the amino acid sequence of SEQ ID NO: 195, which is fully supported by the instant specification.

Claim rejections under 35 U.S.C. 112, second paragraph

Claims 3-6, 8, 15-16, 18, and 36 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. More specifically, claim 3 is rejected as allegedly vague and indefinite as it is allegedly not clear what is the amino acid sequence of a B. microti antigen containing an isolated antigenic epitope comprising the amino acid sequence X1-X5-ser-. Claim 36 is also rejected as being allegedly vague in failing to set forth the intended purpose of the diagnostic kit.

Applicants respectfully traverse these grounds of rejection and submit that based on the instant specification one of ordinary skill in the art would find it clear what amino acid sequences are embraced by claim 3. Nonetheless, solely in order to expedite prosecution of the instant application, claim 3 as well as claims 4-6, 8, and 15 have been cancelled. Claims 16, 18, and 36 have been amended to remove their dependency from claim 3. Claim 36 has also been amended to add the limitation of, "for the detection of B. microti infection" to clearly set forth the intended purpose of the claimed diagnostic kit. Therefore, amended claims 16, 18, and 36 fully comply with the requirements of 35 U.S.C. 112, second paragraph.

Claim rejections under 35 U.S.C. 102

Claims 2, 12, 16, and 18 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Lodes et al (EPO 384567, published on 4/8/1998). Lodes et al disclose an isolated polypeptide of SEQ ID NO:53.

Applicants respectfully traverse the basis of this rejection and submit that Lodes et al. does not disclose an isolated peptide that is identical to the structure and to the function of SEQ ID NO: 195 that are disclosed in the instant application. The specification of the instant application teaches the discrete peptide, BMNI-17-4, of SEQ ID NO:195, that exhibits significant and specific reactivity to the sera of patients infected with the *B. microti* organism (see page 47 of the specification). The specification of the instant applications further teaches the usefulness of BMNI-17-4 as a diagnostic tool for screening human samples for *B. microti* infection. Lodes et al disclose the *B. microti* antigen of SEQ ID NO: 53, but does not teach the identification of a peptide identical in sequence to BMNI-17-4. Therefore, Lodes et al does not provide a disclosure that would enable one of ordinary skill in the art to make or use the BMNI-17-4 peptide, or fusion proteins, compositions, and diagnostic kits of the same. Thus, Applicants respectfully request that this rejection of claims 2, 12, 16, and 18 be withdrawn.

Claims 3-6, 8, and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tetzlaff et al 1990 and Anderson et al 1991. Applicants respectfully submit that the cancellation of claims 3-6 and 8 and amendment of claim 18 herein renders these rejections moot.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **Appendix - Version With Markings to Show Changes Made.**"

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is invited to contact the undersigned at 206-754-5828 with any questions, concerns or suggestions pertaining to this communication.

Respectfully submitted,

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Enclosures:

Postcard

Form PTO/SB/21

Appendix (Version with Markings to Show Changes Made)

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APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The paragraph beginning on page 1, line 5 has been replaced with the following paragraph:

--This application is related to U.S. Patent Application No. 09/794,764, filed February 26, 2001 (pending); U.S. Patent Application No. 09/737,178, filed December 13, 2000 (pending abandoned); U.S. Patent Application No. 09/685,436, filed October 10, 2000 (pending); U.S. Patent Application No. 09/656,688, filed September 7, 2000 (pending abandoned); U.S. Patent Application No. 09/605,724, filed June 27, 2000 (pending abandoned); U.S. Patent Application No. 09/569,098, filed May 10, 2000 (pending allowed); U.S. Patent Application No. 09/528,784, filed March 17, 2000 (pending now U.S. Patent 6,451,315); U.S. Patent Application No. 09/286,488, filed April 5, 1999 (pending); U.S. Patent Application No. 08/990,571, filed December 11, 1997 (pending now U.S. Patent 6,214,971); U.S. Patent Application No. 08/845,258, filed April 24, 1997 (pending now U.S. Patent 6,183,976); U.S. Patent Application No. 08/723,142, filed October 1, 1996 (pending now U.S. Patent 6,306,396); each a continuation-in-part of the previous application and all incorporated herein by reference.--

On page 51 of the application, after the heading "CLAIMS", insert --We claim:--.

In the Claims:

2. (Amended) An isolated polypeptide comprising ~~an the~~ amino acid sequence ~~selected from the group consisting of~~:

~~sequences encoded by a polynucleotide of claim 1; and~~

~~sequences having at least 70% identity to a sequence encoded by a polynucleotide of claim 1;~~

~~sequences having at least 90% identity to a sequence encoded by a polynucleotide of claim 1; and~~

~~sequences selected from the group consisting of SEQ ID NO: 181-203, 207-209 and 211-224. of SEQ ID NO: 195.~~

12. (Amended) A fusion protein comprising ~~at least one~~ the polypeptide according to of claim 2.

14. (Amended) The fusion protein of claim ~~13~~ 12 further comprising a polypeptide having an amino acid sequence of SEQ ID NO:52.

16. (Amended) A fusion protein comprising at least one polypeptide according to ~~any one of~~ claims ~~2, 6 and 8~~, and at least one antigenic epitope according to ~~any one of~~ claims ~~3 and 7~~. of a B. microti antigen comprising an amino acid sequence selected from the group consisting of SEQ ID NOs: 36 and 39.

18. (Amended) A composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulants, and a second component selected from the group consisting of polypeptides according to claim 2 and fusion proteins according to any one of claims 12, 14, and 16.

- (a) ~~polypeptides according to any one of claims 2, 6 and 8;~~
- (b) ~~polynucleotides according to claim 1;~~
- (c) ~~antibodies according to claim 11; and~~
- (d) ~~fusion proteins according to any one of claims 13, 16 and 36.~~

36. (Amended) A diagnostic kit ~~comprising: for the detection of B. microti infection comprising at least one fusion protein according to any one of claims 12, 14, and 16; and a detection reagent.~~ :

- (a) ~~at least one fusion protein according to any one of claims 13, 16 and 35;~~
and
- (b) ~~a detection reagent.~~